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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/301,906	04/29/1999	DENNIS GONSALVES	07678/077002	6222

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CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 05/20/2003

26

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/301,906

Applicant(s)

GONSALVES ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10, 14, 16-18 and 32-67 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 7, 10, 14, 16-18, 32-34 and 36-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6, 35 and 48-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 25. 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 27, 2003 has been entered.

Claims 12 and 19-31 are cancelled.

Claim 6 is newly amended.

Claims 35-67 are newly added.

Claims 1-7, 10, 14, 16-18, 32-67 are pending.

Claims 1-5, 7, 10, 14, 16-18 and 32-34 were previously withdrawn from consideration as being directed to nonelected inventions.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Election/Restrictions

Newly submitted claims 36-47 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: newly submitted claims 36-47 are directed to a process for producing an isolated grapevine leafroll virus nucleic acid sequence. The originally elected invention was directed to isolated nucleic acid sequences encoding a

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grapevine leafroll virus proteinase, and a method of conferring viral disease resistance to a plant or component. The invention set forth in claims 36-47 and the originally elected invention are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the isolated grapevine leafroll virus nucleic acid sequence can be made by another and materially different process, such as chemical synthesis. The invention set forth in claims 36-47 and the originally elected invention are also unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects. The process for producing an isolated grapevine leafroll virus nucleic acid sequence and the method of conferring viral disease resistance to a plant utilize different components and different method steps to produce a different outcome. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 36-47 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

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Information Disclosure Statement

An Initialed and dated copy of Applicant's IDS form 1449, Paper No. 25, is attached to the instant Office action.

Claim Objections

Claims 48-67 are objected to because they depend from claims directed to nonelected inventions. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claim 6 remains rejected, and claims 35 and 48-67 are rejected, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record set forth in the office action mailed May 21, 2002.

Applicant's arguments filed January 27, 2003, have been fully considered but they are not persuasive.

Applicant argues that in light of the amendment of claim 6 which limits the invention to nucleic acid molecules encoding a protein or polypeptide comprising the amino acid sequence of SEQ ID NO:5, no undue trial and error experimentation would be required to identify the nucleic acid molecules encompassed by the claims. (reply page 13).

The Examiner maintains that the claimed invention is not enabled because the specification does not provide sufficient guidance for one skilled in the art to use nucleic acid

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molecules encoding a protein or polypeptide comprising the amino acid sequence of SEQ ID NO:5. Applicant has disclosed the elected nucleic acid sequence of SEQ ID NO:4 which encodes the amino acid sequence of SEQ ID NO:5, and has assigned the structure a function on the basis of homology to the proteinase domain of Hepatitis C virus, but Applicant has not demonstrated a proteinase function for SEQ ID NO:5. As indicated previously, structural homology suggests but does not demonstrate functional homology. For example, Doerks et al. teach that incorrect or incomplete sequence information within a database affects the predictive capacity of the database (Trends in Genetics, 1998, Vol. 14, No. 6, pages 248-250, see page 248 column 1 paragraph 1). Doerks et al. also teach that query searches may identify shared homology with multiple groups of functionally unrelated proteins (Page 248 column 3 second full paragraph), that regions of shared homology may be nonfunctional regions (Page 248 column 3 third full paragraph), and that the degree of shared homology within a functional region does not always predict a conservation of the functional mechanism of that region (Page 248 column 3 fourth full paragraph). Because no functions has been demonstrated for the polypeptide of SEQ ID NO:5, the claimed invention is not enabled by the specification in the absence of further guidance or example.

Furthermore, Applicant also has not demonstrated that expression of a nucleic acid molecule encoding a protein or polypeptide comprising the amino acid sequence of SEQ ID NO:5 will confer any type or amount of viral disease resistance to a transgenic plant. As indicated previously, conferring viral resistance to a plant by expressing a viral proteinase gene is unpredictable. Given the unpredictability of inferring protein function on the basis of structural homology, given the unpredictability of conferring viral resistance to a plant by expressing a

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viral proteinase gene and given the lack of guidance provided by the specification, the Examiner maintains that it would require undue experimentation for one of skill in the art to make and/or use the claimed invention.

Claims 48-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a genus of isolated nucleic acid molecules that are produced by hybridization under high stringency conditions to SEQ ID NO:4 or subfragments thereof.

The specification describes only one isolated nucleic acid molecule that could be produced by hybridization under high stringency conditions to SEQ ID NO:4 or subfragments thereof, the isolated nucleic acid molecule of SEQ ID NO:4 (ORF1a), which encodes a polypeptide of SEQ ID NO:5 having homology to a known viral proteinase (pages 20-22 *Example 1*, page 6 lines 11-12, page 7 lines 23-28). The specification does not describe or characterize any other isolated nucleic acid molecules produced by hybridization under high stringency conditions to SEQ ID NO:4 or subfragments thereof.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119

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F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed product, any method of using it would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No.4/ Friday January 5, 2001/Notices: pp. 1099-1111).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 61-64 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 30 of U.S. Patent No. 5,907,085 (Applicant's IDS). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 61-64 are directed to a transgenic plant or transgenic plant component comprising a DNA molecule encoding a protein or polypeptide comprising the amino acid sequence of SEQ ID NO:5, which is a DNA molecule encoding a protein or polypeptide of a GLRaV-3 grapevine leafroll virus. Claims 1 and 30 of U.S. Patent No. 5,907,085 are directed to a transgenic *Vitis* scion cultivar or rootstock cultivar comprising a DNA molecule encoding a protein or polypeptide of a GLRaV-3 grapevine leafroll virus.

Remarks

No claim is allowed.

Claim 6, 35 and 48-67 are deemed free of the prior art, due to the failure of the prior art to teach or suggest an isolated nucleic acid encoding the amino acid sequence of SEQ ID NO:5.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

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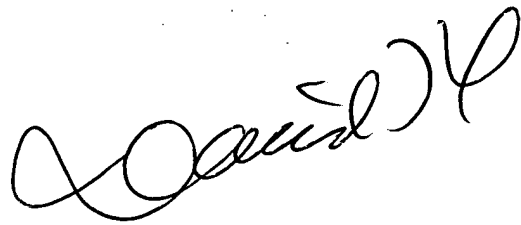
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC

May 19, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638

A handwritten signature in black ink, appearing to read "David T. Fox", written in a cursive style.